

WHAT IS CLAIMED IS:

5 1. A stable pharmaceutical composition comprising a therapeutically effective amount of a biologically active protein and a peptide stabilizer selected from the group consisting of Gly-Gly, Gly-Gly-Gly, Gly-Tyr, Gly-Phe, Gly-His, Gly-Asp, Gly-Ala, Ala-Gly, Ala-Ala, derivatives thereof and mixtures thereof, wherein the composition is free of serum albumin.

5 2. The composition of claim 1, wherein the biologically active protein is selected from the group consisting of erythropoietin, Factor VIII, Factor IX, granulocyte colony stimulating factor, granulocyte macrophage colony stimulating factor, interferon alpha, interferon beta, interferon gamma, interleukin 2, follicle stimulating hormone, insulin-like growth factor, nerve growth factor, BMP-2, BMP-4, BMP-7, and tumor necrosis factor.

3. The composition of claim 2, wherein the biologically active protein is of recombinant origin.

4. The composition of claim 3, wherein the biologically active protein is erythropoietin.

5. The composition of claim 4, wherein the erythropoietin is erythropoietin omega.

6. The composition of claim 5, wherein concentration of erythropoietin omega in said composition is between about 500 IU/ml and about 100,000 IU/ml.

7. The composition of claim 6, wherein the concentration of erythropoietin omega is between about 2,000 IU/ml and about 20,000 IU/ml.

8. The composition of claim 1, wherein the derivatives comprise salts of Gly-Gly, Gly-Gly-Gly, Gly-Tyr, Gly-Phe, Gly-His, Gly-Asp, Gly-Ala, Ala-Gly, and Ala-Ala.

9. The composition of claim 1, wherein the serum albumin is human serum albumin.

10. The composition of claim 1, wherein concentration of the peptide stabilizer in said composition is between about 0.01 g/L and about 10 g/L.

11. The composition of claim 10, wherein the concentration of the peptide stabilizer is between about 0.5 g/L and about 5 g/L.

12. The composition of claim 1, wherein the composition further comprises a surfactant.

13. The composition of claim 12, wherein the surfactant is a nonionic surfactant, cationic surfactant, anionic surfactant, amphoteric surfactant, zwitterionic surfactant, or a mixture thereof.

14. The composition of claim 13, wherein the surfactant is a polyoxyalkylene sorbitan fatty acid ester.

15. The composition of claim 12, wherein concentration of the surfactant in said composition is between about 0.0005% w/v and about 0.5% w/v.

16. A stable pharmaceutical composition comprising erythropoietin and a peptide stabilizer selected from the group consisting of dipeptides, tripeptides, tetrapeptides, pentapeptides, and mixtures thereof, and wherein the composition is free of serum albumin.

17. The composition of claim 16, wherein the peptide stabilizer is a dipeptide.

18. The composition of claim 16, wherein the peptide stabilizer is a tripeptide.

19. The composition of claim 16, wherein the peptide stabilizer is selected from the group consisting of Gly-Gly, Gly-Gly-Gly, Gly-Tyr, Gly-Phe, Gly-His, Gly-Asp, Gly-Ala, Ala-Gly, Ala-Ala, derivatives thereof, and mixtures thereof.

20. The composition of claim 19, wherein the derivatives comprise salts of Gly-Gly, Gly-Gly-Gly, Gly-Tyr, Gly-Phe, Gly-His, Gly-Asp, Gly-Ala, Ala-Gly, and Ala-Ala.

21. The composition of claim 16, wherein concentration of the peptide stabilizer in said composition is between about 0.01 g/L and about 10 g/L.

22. The composition of claim 21, wherein the concentration of the peptide stabilizer is between about 0.5 g/L and about 5 g/L.

23. The composition of claim 16, wherein the serum albumin is human serum albumin.

24. The composition of claim 16, wherein the erythropoietin is a recombinant erythropoietin.

25. The composition of claim 24, wherein the recombinant erythropoietin is produced in BHK cells.

26. The composition of claim 24, wherein the recombinant erythropoietin is produced in CHO cells.

27. The composition of claim 24, wherein the recombinant erythropoietin is erythropoietin omega.

28. The composition of claim 27, wherein concentration of erythropoietin omega in said composition is between about 500 IU/ml and about 100,000 IU/ml.

29. The composition of claim 28, wherein the concentration of erythropoietin omega is between about 2,000 IU/ml and about 20,000 IU/ml.

30. The composition of claim 16, wherein the composition further comprises a surfactant.

31. The composition of claim 30, wherein the surfactant is a nonionic surfactant, cationic surfactant, anionic surfactant, amphoteric surfactant, zwitterionic surfactant, or a mixture thereof.

32. The composition of claim 31, wherein the surfactant is a polyoxyalkylene sorbitan fatty acid ester.

33. The composition of claim 30, wherein concentration of the surfactant in said composition is between about 0.0005% w/v and about 0.5% w/v.

34. A stable pharmaceutical composition comprising erythropoietin, a polyoxyalkylene sorbitan fatty acid ester, and a peptide stabilizer selected from the group consisting of Gly-Gly, Gly-Gly-Gly, Gly-Tyr, Gly-Phe, Gly-His, Gly-Asp, Gly-Ala, Ala-Gly, Ala-Ala, derivatives thereof and mixtures thereof, wherein the composition is free of serum albumin.

35. The composition of claim 34, wherein the erythropoietin is erythropoietin omega.

36. The composition of claim 34, wherein the serum albumin is human serum albumin.